



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

perused 3/2/99 NAW
HFI-35
M24357

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-12-99W

March 1, 1999

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael J. Fitzgerald, Owner and President
Fitzgerald's Inc.
dba Schermerhorn's Seafood
224 Westfield Road
Holyoke, Massachusetts 01040

Dear Mr. Fitzgerald:

On November 23, and 24, 1998, the Food and Drug Administration (FDA) conducted an inspection of your seafood processing plant, located at 224 Westfield Road, Holyoke, Massachusetts. The Investigator documented serious violations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123), and the Good Manufacturing Practices (GMPs) requirements in 21 CFR 110. These violations cause your fish and fishery products processed by your firm, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

- Failure to have and implement a written HACCP plan for tuna and mahi mahi, when one is required to control the hazard of histamine which is reasonable likely to occur in these products.
- Failure to maintain sanitation control records (21 CFR 123.11(c)) that document the monitoring and corrections of sanitation conditions specified in the regulations.

Fitzgerald's, Inc.
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224 Westfield Road
Holyoke, Massachusetts 01040
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The above identification of violations are not intended to be an all-inclusive list of deficiencies at your seafood processing plant. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export for tuna and mahi mahi processed at your facility until your firm is fully in compliance with the seafood HACCP regulations.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation demonstrating that corrections have been made. If corrections cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Bruce R. Ota, Compliance Officer, at the noted above. If you have any questions concerning this matter, please contact Mr. Ota at (781) 279-1675, x119.

Sincerely,

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John R. Marzilli
District Director
New England District Office

NWE:JRM/GTC/BRO

cc: CF1294191, LR, R, GTC, BRO, WL, State of MA (purged) w/cover, HFI-35 (purged), HFC-210, HFA-224, HFS-607, HFR-NE12, HFR-NE250, HFR-NE200, HFR-NE245 (purged)